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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,605	09/29/1998	TOM DE VRINGER	98.554	8895

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/155,605

Applicant(s)

DE VRINGER ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-17 and 19-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-17 and 19-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment dated 9-26-05 is acknowledged.

Claims included in the prosecution are 1-9, 12-17 and 19-37.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9, 12-17 and 19-37 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 521 562 of record.

EP 0521 562 teaches instant reverse vesicles containing sucrose fatty acid esters and an apolar vehicle, which is a silicone oil or isoparaffin. The compositions further contain a lipophilic stabilizing factor such as cholesterol and an active agent. The process of preparation involves making a dispersion of reversed vesicles from the non-ionic surfactants and the active agent in an apolar (non-polar) vehicle such as volatile silicone oil and removing the non-polar vehicle (note the abstract, col. 5, line 49 through col. 12, line 56, Examples and claims). Although EP does not explicitly teach that the preparation is in the form of a powder, since it teaches on col. 12, lines 55-56, the removal of the non-polar vehicle (volatile silicon oil), the teachings of a powder form of the preparation are implicit in the reference.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that EP 562 discloses dispersions of reversed vesicles,

Art Unit: 1615

prepared from different types of vesicle-forming compounds and apolar carrier materials and though the document on column 12, lines 55-56 mentions that the non-polar excipients is to be removed to obtain instant product, there is no teaching or even suggestion of how to do it. These arguments are not persuasive. First of all, EP teaches vesicle-forming compound, sucrose fatty acid ester just as in instant invention (see instant claim 6). With regard to applicant's arguments that the reference does not teach how to remove the non-polar excipients, the examiner points out that as recognized by applicant himself the reference teaches the removal of the non-polar excipients and since this oil is volatile, the reference does not have to teach how to do it; it is within the skill of the art.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1615

2. Claims 1-9, 12-17 and 19-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0521562 by itself or in further combination with EP 0 678 295, EP 0159237, GB 2002319, JP 05194253 by themselves or in combination (all are of record).

According to instant claims, the preparation is a reversed vesicle, meaning that the hydrophobic group of the surfactant molecule is oriented toward the hydrophobic continuous medium, which is an oil (silicone oil).

As pointed out above, EP 0521 562 teaches instant reverse vesicles containing sucrose fatty acid esters and an apolar vehicle, which is a silicone oil or isoparaffin. The compositions further contain a lipophilic stabilizing factor such as cholesterol, a hydrophilic stabilizing factor, and an active agent. The process of preparation involves making a dispersion of reversed vesicles from the non-ionic surfactants and the active agent in an apolar (non-polar) vehicle such as volatile silicone oil and removing the non-polar vehicle (note the abstract, col. 5, line 49 through col. 12, line 56, Examples and claims). What this reference lacks are the explicit teachings that the preparation is in the powder form.

EP 0678 295 teaches that vesicular preparations (hydrophilic group of the lipid is oriented towards the continuous external phase (water) can be lyophilized to form powders (note Example 1 and claims 1 and 7).

EP 0159237 teaches that emulsions (micelles) can be freeze-dried to form powders, which are easier to handle than emulsions (note the abstract).

Art Unit: 1615

GB teaches that dehydration of lipid vesicles (liposomes) to prepare a stable powder, which can be stored for longer periods of time (note the abstract).

JP 05194253 teaches the preparation of a powder of reverse micelles containing a surfactant (note the abstract).

Assuming that the preparations taught by EP 0521 562 are not powder preparations, it is deemed obvious to one of ordinary skill in the art that if the removal of the external medium in which the vesicles are dispersed results in a powdery preparation as evidenced by the references of the references of EP 295, EP 237 and JP 253. One of ordinary skill in the art would be motivated to remove the external medium such as volatile silicone oil and prepare the powders since GB teaches that powders are stable and can be stored for longer periods of time.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that EP (526?) relates to stable dispersions of reversed vesicles in biodegradable oil, but does not teach or suggest a method of making the instantly claimed powder of reversed vesicles. The examiner disagrees; as pointed out above, EP 562 teaches reverse vesicles containing sucrose fatty acid esters and an apolar vehicle, which is volatile silicone oil and the removal of oil. Instant claims do not differentiate from the prior art product.

Applicant argues that EP 295 relates to a completely different issue than EP 562 and not concerned with increasing the amount of the liposome vehicle, let alone reversed vesicles. Applicant argues that EP 237 relates to oil-in-water emulsions, inaccuracy of dosing, incompatibility of active ingredients, etc., and does not relate to

Art Unit: 1615

vesicular systems at all. Applicant argues that GB aims at providing a solution for the short shelf life of liposomes by providing a process for the dehydration of the liposomes to obtain a powder, which can be stored for a longer period and from which liposome dispersion can be reconstituted. Applicant argues that JP relates to the preparation of a reversed micelles containing solution as a first step in the preparation of polymer microcapsules and that there is no mention of increasing the percent yield of micelles/microcapsules. These arguments are not persuasive. First of all, the primary reference, EP 562 itself teaches the removal of the non-polar medium and applicant previously argued that the reference does not teach how it is removed. The secondary references clearly show the skill in the art of preparing powders from micelles, reverse micelles and vesicles and therefore, the preparation of powders or reverse micelles by the removal of the volatile medium in EP 295 by art known techniques would have been obvious to one of ordinary skill in the art. Applicant's arguments with regard to unexpected results are not persuasive. Applicant argues that there is no teaching or suggestion or other evidence from which one of ordinary skill in the art could have expected that the presently claimed method would produce a powder of reversed vesicles that when dispersed in a biodegradable oil would result in a percent of reverse vesicles that is greater than the percent resulting from preparation of reversed vesicles directly in the biodegradable oil. A careful review of the specification indicates that it does not contain any data of the encapsulation before the preparation of the powder which would enable one to determine whether the differences observed are significant or not and unexpected or not. The prior art of record clearly indicates the

Art Unit: 1615

knowledge in the art of preparing the reverse vesicles and the preparation of powders by dehydrating either micelles or vesicles and one would be motivated to remove the solvent from reverse vesicles of EP 562 to prepare powders with a reasonable expectation of success.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK